

**Remarks**

Applicants request entry of the amendments. The amendments place the application in condition for allowance.

Initially, applicants respectfully request an Examiner's Interview to discuss the amended claims in light of the voluminous record of Interference Decisions. Applicants' representative will contact the Examiner to arrange a convenient time.

Claims 1-35 and 40-42 have been canceled.

Applicants herein amend claims 36-39 to recite a replication defective adenovirus comprising, in addition to E4 genes, optionally E1 and E3 genes, which have been rendered non-functional. Applicants also specified that the adenovirus is a human group C adenovirus. Support for these amendments can be found in the specification, for example at page 5, lines 11-17 and in Example 5. The Examiner suggested these amendments to claims 36-39 at page 11 of the Office Action.

Applicants also add new claims 43-84.

Claims 43 and 44 are directed to a human embryonic kidney 293 cell line comprising adenoviral genes. These claims were suggested by the Examiner at pages 2-3 of the Office Action. The Examiner suggested these claims in light of decisions of the Board of Patent Appeals and Interferences in Interference Nos. 104824, 104828, 104829 and 104830. Applicants have also added, consistent with the decisions of the Board, new claims 45-84.

Claim 45 recites a replication defective recombinant human group C adenovirus wherein the E1 and E4 genes have been rendered non-functional. Support for this claim can be found in the specification, for example, at page 3, line 34 to page 4, line 5 and Example 5. The Board indicated that this combination of non-functional genes is enabled. See Interference No. 104,830, Paper 116, at page 70 (see description of deletions in gene functions for  $\Delta E1\Delta E4$  at top of page).

Claim 53 recites the replication defective recombinant adenovirus of claim 45, wherein the E3 genes have additionally been rendered non-functional. Support for this claim can be found in the specification, for example, at Example 5. The Examiner suggested this combination of non-functional genes at page 11 of the Office Action.

Claim 61 recites a replication defective recombinant human group C adenovirus wherein the E1 and E2A genes, and optionally E4 genes, have been rendered non-functional. Support for this claim can be found in the specification, for example, at page 3, line 34 to page 4, line 5. Since the Examiner indicated at page 11 of the Office Action that the complementing cell line would be allowable, the recombinant adenovirus would logically be allowable.

Claims 46-52, 54-60 and 62-68 are dependant on claims 45, 53 and 61, respectively, and further define the characteristics of the adenoviruses. Support for these claims can be found in the specification, for example, at page 6, line 29 to page 9, line 7.

Claim 69 is directed to a cell line that complements the adenovirus of claim 45. Support for this claim can be found in the specification, for example, at page 12, lines 5-13 and Example 4. Since the Board's Decision indicated that the recombinant adenovirus of claim 45 is enabled, the complementing cell line would logically be enabled.

Claim 73 is directed to a cell line that complements the adenovirus of claim 53. Support for this claim can be found in the specification, for example, at page 12, lines 5-9. Since the Examiner indicated that the recombinant adenovirus of claim 45 is enabled, the complementing cell line would logically be enabled.

Claim 77 is directed to a cell line that complements the adenovirus of claim 61. Support for this claim can be found in the specification, for example, at page 12, lines 5-13. The Examiner indicated at page 11 of the Office Action that this claim would be allowable.

Claims 70-72, 74-76 and 78-80 are dependent on claims 69, 73, and 77, respectively, and further define the characteristics of the cell lines. Support for these claims can be found in the specification, for example, at page 12, lines 9-13 and Example 4.

Claims 81-84 are directed to compositions comprising the claimed replication defective recombinant adenoviruses. Support for these claims can be found in the specification, for example, at page 12, lines 14-20.

Claims 36-39 and 43-84 are pending after entry of the amendments.

No new matter enters by these amendments.

Applicants have amended the claims in accordance with the Examiner's suggestions and the Interference Decisions and submit that all of the above claims are allowable. The responses to specific rejections noted below address only those issues where applicants disagree with the Examiner's reading of the decisions.

#### **Response to Claim Objections**

The Examiner objects to claims 6, 10, 19-27, 29 and 33 as depending from claims that stand finally disposed of and states that claims 6, 10 and 19 should be rewritten in independent form. Applicants note that claims 6, 10, 19-27, 29 and 33 have been canceled. The subject matter of claim 19 has been incorporated into new claim 77. The Examiner suggested the language for the claim 19 subject matter at page 11 of the Office Action. This language has been incorporated into new claims 77 and 61.

Applicants respectfully request withdrawal of this objection.

#### **Response to Rejections for Written Description**

The Examiner rejects claims 10, 19-26, 29 and 33 under 35 U.S.C. § 112, first paragraph, for failure to comply with the written description requirement. Applicants note that claims 10, 19-26, 29 and 33 have been canceled. The subject matter of claim 19 has been incorporated into new claim 77. The subject matter of claims 19, 20-22, 24 and 26, which were dependent on claim 19, has been incorporated into new claim 77. The subject matter of claim 23 has been incorporated into new claim 78, and the subject matter of claim 25 has been incorporated into new claim 79.

The Examiner rejects claim 19 as containing new matter because it allegedly embraces embodiments wherein the E1 complementing sequence is under the control of an inducible promoter. New claim 77 recites a cell line wherein the E1 gene is under the control of its own promoter.

Applicants respectfully request withdrawal of this rejection.

**Response to Rejections for Lack of Enablement**

The Examiner rejects claims 6, 10, 19-27, 29, 33, and 36-39 under 35 U.S.C. § 112, first paragraph, for failure to comply with the enablement requirement. Applicants note that claims 6, 10, 19-27, 29 and 33 have been canceled. The subject matter of claim 19 has been incorporated into new claim 77. The subject matter of claims 20-22, 24 and 26, which were dependent on claim 19, has been incorporated into new claim 77. The subject matter of claim 23 has been incorporated into new claim 78, the subject matter of claim 25 has been incorporated into new claim 79, and the subject matter of claim 27 has been incorporated into new claim 80.

The Examiner rejects claim 19 as not enabled because it allegedly embraces embodiments wherein the E2 genes are not under the control of an inducible promoter. New claim 77 recites a cell line wherein the E2A gene is under the control of an inducible promoter. Claims 19-27 also stand rejected for allegedly failing to enable the making of cell lines that must complement adenoviral vectors deficient in multiple E2 genes as well as late genes. New claim 77 recites a cell line that complements the E2A gene and no late genes.

Claims 36-39 have been amended to recite a replication defective recombinant adenovirus comprising non-functional E4 genes, and optionally nonfunctional E1 and E3 genes. The Examiner suggested this amendment in the Office Action at page 11. Applicants also amended claims 36-39 to recite a human group C adenovirus. See Office Action, at page 9.

Applicants respectfully request withdrawal of this rejection.

**Response to Provisional Rejections for Double Patenting**

The Examiner provisionally rejects claims 6, 10, 19, 20, 23, 25-27, 29 and 36-39 under 35 U.S.C. § 101 as claiming the same invention as that of claims 34, 36, 45-50, 52 and 56-59, respectively, of co-pending Application No. 10/301,085.

The Examiner provisionally rejects claims 21, 22, 24 and 33 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 45, 46, 62, 76-80, 83 and 84 of co-pending Application No. 10/301,085.

Appl. No. 08/397,225  
Reply and Amendment dated November 7, 2005  
Reply to Office Action of May 5, 2005


As there are no allowed claims and the claims of this application have been amended, applicants will address the provisional double patenting rejections after claims in either of the pending applications have been allowed.

The application is in condition for allowance. Timely notification of allowability is requested.

If there are any additional fees due with the filing of this document, including fees for the net addition of claims, applicants respectfully request that any and all fees be charged to Deposit Account No. 50-1129. If any extension of time request or any petition is required for the entry of this paper or any of the accompanying papers, applicants hereby petition or request the extension necessary. The undersigned authorizes any fee payment from Deposit Account No. 50-1129.

Respectfully submitted,  
**Wiley Rein & Fielding LLP**

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